
Code of Ethical Principles for Genetics Professionals: An Explication

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PREAMBLE

Genetics impacts the health of all individuals, their offspring, and future generations. The practice of medical genetics has generated principles of ethics to guide those who strive to serve humanity within this profession. The principle tenets are presented for the guidance of each professional and for the information of the public. The evolution of these principles should be only in the direction of higher levels of service to both the individual and the community, and enhancement of the freedom and rights of those who come under the care of anyone belonging to the profession.

Though families with identified genetic conditions currently represent a relatively small segment of the population, virtually everyone is touched by genetics services. Genetic screening is offered to every pregnant woman who receives timely prenatal care, and is provided by law to every newborn. With the advent of presymptomatic and susceptibility testing, the possibility arises of preventive care, but also of unjust discrimination.

As testing and treatment options continue to increase in number and complexity, more choices become available. This evolution has been driven by the conviction that substantial benefits accrue to consumers when such services are appropriately provided. However, members of the profession have long recognized that disclosure of genetic status may adversely affect the autonomy and privacy of the individual, and may have profound effects on other family members.

Much has been written about the ethics of genetic information-giving and about the proper uses of genetic technologies. We have attempted here to collect statements of ethical practice on which a consensus exists. As consensus evolves among genetics professionals and consumers in other areas of practice, additional principles should be added. Inclusion of new statements should be by the consensus of the committee appointed by Council of Regional Networks (CORN), with acceptance by vote of the CORN Steering Committee.

This collection of statements is directed to all professionals who are involved in genetics services on any level. While contemplation of this collection is of bene-

fit to the professional and those entering the profession, it may have its greatest value for the consumer of genetics services. Almost every statement has the benefit of the consumer as its focus, and the autonomy of the informed consumer is given preeminence.

These statements have drawn on previous documents already accepted by elements of the profession. Of note are the codes of the National Society of Genetic Counselors [1992] and the Canadian College of Medical Genetics [1986] and the Ethical Manifesto published by VSOP [1990] in the Netherlands. The Committee became aware of a draft of an important document by Wertz and Fletcher [1995] for the WHO after it had written the Code of Ethical Principles for Genetics Professionals. This document is now available.

RESPONSIBILITIES TO PATIENTS AND FAMILIES

The relationships among genetics professionals, patients, and their families are founded on the principles of autonomy and privacy.

The principles of autonomy and privacy are recognized as fundamental to the contemporary physician-patient relationship. These ethical concepts reinforce the partnership between the genetics professional and the patient, and recognize the patient as the primary decision-maker in the relationship. The principle of autonomy acknowledges the patient as a competent individual who is capable of understanding options and of making his or her own choices. The concept of privacy is derived from the principle of autonomy: privacy implies respect for the person, in the sense both of the physical body and of mental and emotional well-being. These general concepts require that the genetics professional adopt the following guidelines for respecting relationships with patients and their families. While the genetics professional is expected to act in a beneficent manner, it is difficult to codify the aspects of this principle.

The genetics professional should:

1. Serve patients and their families with equity and with respect for each person's feelings, beliefs, ethnocultural traditions, and social circumstances.

The genetics professional should strive to provide services with equity for all who seek their help, and to ensure that all segments of society are included in these services. Equity implies that services will be

Received for publication February 16, 1995; revision received October 23, 1995.

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provided without regard to race, sex, age, religion, disabilities, genetic status, or financial or social circumstances. Equity also includes respect for individual opinions and principles and for ethnic background and values.

2. Provide counseling that is nondirective, supportive, and responsive to the individual's requests, and respect the choices of patients and families.

The genetics professional should strive to provide counseling that does not direct the patient toward any particular decision or course of action. The reason for this approach is to guard against any hint of coercion in the relationship between the genetics professional and the patient. Counseling should be supportive when the patient clearly indicates a decision or course of action that is appropriate with respect to personal circumstances and ethical principles. Counseling that is responsive to individual requests acknowledges that patients have personal views which may differ from those of the genetics professional. Counseling also acknowledges that patients and their families may make choices which differ from those that the professional might prefer. Requests from the patient for professional opinion and advice may be honored.

On the other hand, the genetics professional is not required to abandon his or her own professional or ethical principles because of a patient's decision or request. Some patients have unique points of view or traditions that do not reflect the views or traditions of the majority of society. While the genetics professional should counsel with respect for individuality, the geneticist may oppose any requests or decisions that may endanger other individuals or impinge unfairly on their rights. This opposition should acknowledge the tension that arises between the professional and the patient. It should also include discussion of the professional's reservations about the patient's decision or requests. When the patient's decision or request is clearly unacceptable to the professional, the professional should state his or her reservations clearly and refer the patient as necessary to other professionals who might be more sympathetic to that patient's point of view. Both the patient and the professional should understand that the professional obligation extends to referral, and that no sense of abandonment is intended.

3. Convey information sensitively to patients, and in language they understand, so that they may make independent decisions and give informed consent.

The genetics professional-patient relationship is a fiduciary relationship typically characterized by an imbalance between the knowledge and expertise of the professional and of the patient. The genetics professional has an obligation to assess the extent of the patient's knowledge and understanding, and to communicate with the patient in appropriate language and levels of complexity. Information that is exchanged during the course of genetic counseling must be sensitive to the patient's circumstances without patronizing or stereotyping the patient or the patient's family. Information should include thorough discussion of community resources available to the patient, including dis-

cussion of various support groups and their publications and activities. The genetics professional should always be aware that patients have the right to make their own independent decisions, as well as the right to be informed for purposes of making these decisions and for giving informed consent.

4. Refer, when indicated or requested, to other experts for specialized services or to confirm diagnosis.

The genetics professional should always be cognizant of the limits of his or her own expertise and of the limits of professional care available in his or her own institution. This awareness includes an appreciation of the expertise of other professionals, their areas of specialization, and their potential contributions to the care of a particular patient or family. The professional obligation includes willingness to refer patients for specialized services, and also a willingness to consider the patient's particular capacity and means to seek further help elsewhere.

5. Honor the confidentiality of information shared in the relationship with patients and their families.

Confidentiality of information exchanged between the genetics professional and the patient is derived from the patient's rights to autonomy and privacy. The patient's voluntary informed consent is necessary for sharing any information with other medical or genetics professionals. Prior consent should be obtained whenever it can reasonably be anticipated that sharing information will be necessary.

6. Urge patients and families to share genetic information with relatives at risk, pointing out the possible need for this early in the relationship.

By its nature, genetic information often extends beyond the individual or the immediate family. Tension naturally arises between the desire of many individuals and families to keep information confidential, on the one hand, and the concern of the genetics professional, on the other hand, to inform members of the extended family about their potential risks. The genetics professional should always act from a presumption of protecting the confidentiality of genetic information. However, on occasion, the genetics professional may face an exceptional situation in which great harm may occur if information is not disclosed to relatives who are at genetic risk. The genetics professional should first explain to the patient the necessity of conveying this information to members of the extended family. If the patient is unwilling or unable to communicate with other members of the family, the genetics professional may, under some infrequent circumstances, override the presumption of confidentiality after informing the patient of the gravity of the circumstances and the obligation to notify other family members. (U.S. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1983).

7. Inform persons who participate as subjects of research that they may refuse testing, or refuse to receive information, and that they may withdraw from research programs without change in care.

Many genetics professionals are active in research and testing in human and medical genetics. Profession-

als have an obligation to impart complete information to participants or their parents about their options with regard to testing or cooperation in research protocols. These options include voluntary participation, the right to refuse testing, the right to refuse to receive any information that is generated by testing or research programs, and the right to withdraw at any time without any change in care, noninvestigational treatment, or support.

The genetics professional should be candid with participants about his or her professional interest in research and about his or her role in developing new knowledge about human and medical genetics. The professional should also be candid about dual interests in improving patient care and about academic expectations to contribute to new advances. The professional should always be aware that the refusal of an individual to participate in testing or research is not a negative reflection on his or her professional competence.

8. Inform patients of possible conflicts of interest and of possible commercial and other uses of their biological specimens, of duration of storage, and of confidentiality of personal identifiers.

The expansion of genetic technologies has created many possibilities for the use of biological specimens after completion of the genetic tests for which the samples were originally collected. The genetics professional should inform patients, participants, or their parents about the possible future use of these specimens in genetic research. Patients are also entitled to know about the possibility of commercial interests in derivatives of biological specimens. The genetics professional should always inform patients or participants about policies for storing biological specimens and about the possibility of future use of specimens without identifiers. Individuals who are sources of biological specimens should be accorded the opportunity to refuse any future use of samples that they have supplied.

RESPONSIBILITY TO SOCIETY

Individuals within the professional genetics community have a responsibility to provide assistance to society as a whole in the understanding of genetics. Genetics professionals should:

1. Participate actively in the development and support of appropriate regulation of genetic services to ensure that the highest quality is maintained.

There is constant growth in the availability of genetic tests and genetic treatment. Likewise, the methods of delivering health care change, the very nature of health care services is constantly reviewed, and policies for reimbursement of health care costs are in a state of flux. This combination presents a threefold challenge in which the involvement of genetics professionals is crucial.

Access

First, decisions must be made regarding which genetics services are offered by whom within the health care system. This is especially critical in light of the

growing commercial availability of genetic tests and the decreasing availability of genetic counseling services in some health care settings. The genetics community should work with legislative and regulatory agencies to determine the content and availability of services which must be included as a reimbursable part of basic health care.

Clinical Services

Second, the voice of the genetics professional is essential in urging that genetic testing be provided only in concert with basic genetics services which include adequate and appropriate counseling; that genetics services be provided only by primary or specialty programs which meet the established standards of quality; and that appropriate practice standards be developed which encompass new tests and services as they become available.

Laboratory Services

The third aspect involves the development of appropriate and timely regulations to ensure the qualifications of professionals involved in genetic testing and the safety and efficacy of diagnostics and reagents used in genetic tests. Often, technological innovations and the understanding of clinical benefit far outpace the regulatory responses. Input from genetics professionals is essential in such situations, to assist in and encourage the formulation of appropriate regulatory schemes.

2. Achieve appropriate balance between the rights of individuals and the needs of public health in the use of genetic information.

The principle of autonomy encompasses both the individual's right to privacy and the expectation of confidentiality. The right of privacy protects the individual from unwarranted intrusion into his or her personal matters. The expectation of confidentiality assures the individual that his or her personal information will not be divulged without consent. While autonomy is a central principle of bioethics, it is not an absolute right. Public health programs, designed to foster the health and well-being of society, can include features which impinge upon individual autonomy. In the case of genetics, mandatory screening programs may violate personal privacy. Mandatory reporting of genetic test results may divulge personal information without consent. Only when the benefits of a public health program clearly warrant limitation of autonomy, and only when such limitations are as circumscribed as possible, can public health programs be ethically promoted. Genetics professionals, including individuals with the appropriate ethical training, should offer essential insight into the process of establishing the optimal public-private balance in acquisition and use of genetic information.

3. Promote educational activities designed to inform the community of developments in genetics, and assist the community in formulating reasonable expectations and in understanding implications.

The rapid growth of genetic technology and genetic information frequently becomes headline news. The popular press asks if infidelity might be in our genes.

Lawyers in a highly publicized murder case assert that a "genetic history of violence" is a defense to the charge of first-degree murder. The cloning of genes for disorders such as breast cancer, cystic fibrosis, colon cancer, etc. is frequently described in a way that creates false hopes of fears and unrealistic expectations. The examples are endless. The common challenge throughout all of the sensationalism is the need to establish a realistic understanding of what genetic information can and cannot explain, and to resist the temptation to use genetic information as a simplistic explanation for complex medical and social situations. Because of the highly technical nature of medical genetics, input from genetics professionals is essential in shaping and promoting reality-based community educational activities. Examples of these types of educational activities include speaking to all segments of society (such as media professionals, and academic, community, and support groups), and responding (when appropriate) to misleading statements in the media.

4. Stimulate public discussion of issues arising from advances in genetics, ensure that public debates include objective and well-documented science, and participate in formulation of public policy and attitudes towards genetics to promote socially responsible change.

The genetics professional has a responsibility to the profession and to society to be an advocate for genetics. This includes advocating the inclusion of accurate information on genetics and genetic testing and services in public education beginning with primary school and continuing through all educational levels. The professional should strive to ensure that public discussion and/or debate be founded on objective, well-documented science to avoid decisions based on misinformation and reaction to emotionally-laden terms.

Public policy is largely formulated by public officials. Genetics professionals should provide these individuals with information about genetics and genetic technology so that laws are based on valid genetic science and its social implications.

5. Distinguish, in public statements, between fact, professional consensus, competing schools of thought, or personal opinion.

The genetics professional should clearly indicate the degree to which genetic information represents consensus of expert opinion or accepted fact, so that accurate and accurately identified information may be disseminated to society. Fact, professional consensus, schools of thought, and opinion all have a role to play in advancing knowledge of genetics, but the categories must be identified as such.

6. Guard against discrimination on the basis of genetic status, race, gender, sexual orientation, religion, or socioeconomic status in the provision of genetics services.

The principles of equity and justice demand that each individual using genetics services be provided such services as are appropriate based on medical need independent of race, gender, sexual orientation, age, religion, genetic, or socioeconomic status. Artificial barriers that limit access, such as location of services, choice of media, or language, should be eliminated.

Race and ethnicity are concepts that are difficult to define but which are of greater use in genetics than in many other specialties. Some genetic disorders, while not exclusive to any one group, have a higher incidence in some groups than in others. Guarding against discrimination includes a determination of the racial and ethnic composition of the population served so that genetics programs are appropriately designed.

7. Support equitable access to genetics services as part of any health care system.

The first barrier to access in many cases is financial. Therefore, genetics professionals should be committed to removing financial barriers to health care. Whenever genetic resources are limited, the genetics professional should address the issues of quality and use of genetic resources based upon social responsibility, the needs of the community, and ethical cost-benefit analysis. Equitable access implies universal access to all medically necessary services.

8. Support regulation of genetic research that provides ethical standards, including informed consent and confidentiality.

Participation in research must be voluntary. Individuals participating in research should be fully informed about the potential risks and benefits of the research proposed, so that they can exercise their right of consent. Because genetic research most often involves more than one person in a family, confidentiality can sometimes become problematic. As computer and other means of communications expand, confidentiality and privacy require new and stronger safeguards.

9. Use genetic knowledge and techniques to support and broaden the choice of patients, and not promote eugenic programs.

Patients should be given information in a language and at a technical level they understand. The person giving the information should recognize the he/she has biases and must try to be noncoercive. The personal choice to use or not to use genetic technology will depend on the beliefs and values of the individual or couple. Culture, ethnic origin, and religion will greatly influence choice; and choice must be allowed. Choice is the option to say "yes" or "no."

We have now developed or are developing technology which may have eugenic consequences. If such technologies are to be adopted, there should be careful consideration of all consequences, intended and unintended, and individual choice must be preserved. Genetics professionals and society should support individuals with genetic differences.

RESPONSIBILITIES TO THE PROFESSION

Individuals within the professional genetics community have a responsibility to provide assistance to society as a whole in the understanding of genetics. Genetics professionals should:

1. Maintain professional competency through continual learning.

Professionals in genetics as in other fields require continuing education to maintain high-level skills. Ge-

netics is characterized by unusually rapid development in technologies and in information.

2. Share expertise attained through training, experience, and research by teaching, publishing, collegial interchange, and nurturing those who seek competency in the disciplines.

The reciprocal learning process which characterizes our interactions with patients, colleagues, and students is acknowledged in most medical codes. Our professional knowledge base evolves through the efforts of colleagues who make their learning available to the wider professional community. Each genetics professional is obligated to contribute to this effort.

3. Support and encourage one another in ethical conduct, and in resolving professional differences with mutual respect and for the benefit of the patient.

Without the encouragement and support of colleagues, the genetics professional cannot expect to maintain courage and creativity in the face of challenging clinical problems. Nor will the geneticist be perceived as a productive member of society without offering the same support to others. Opinions may differ on both scientific and social issues. Yielding to the temptations of personal criticism or self-aggrandizement demeans the profession and the professional. Focusing on professional rivalry rather than on the patient is a failure in professional responsibility.

4. Share appropriate information with the referring source, toward the collaborative development of a plan of care for the patient.

Genetics professionals function as consultants to a variety of referral sources, including social workers and teachers as well as medical professionals. As such, they cooperate in the development of a care plan embracing all the disciplines required to meet the needs of the patient. Timely and appropriate information provided by the genetics professional is integral to the development of fruitful interactions among providers, the patient, and the family. In the event of a professional disagreement regarding the plan of care, the patient should be informed of the geneticist's recommendations.

5. Guard against the profession's limiting, or cooperating in the limiting, of any individual's or group's human rights on the basis of genetic characteristics.

Genetics professionals may voice expert opinions as well as personal convictions towards the development of public policy regarding genetic technologies. Both the profession and individual professionals should guard against limiting a patient's decision-making rights by withholding information or appropriate services. Each professional has the right in conscience to decide what procedures in what circumstances he or she will perform, but has no right to withhold information or to persuade the patient to undertake a course of action based on the personal convictions of the professional. Neither the profession nor the individual genetics professional should participate in limiting the rights of any group because of genetic characteristics or in using genetic technology to identify any group subject to unjust discrimination. Refusal to cooperate with an unjust law is the duty of each professional and of the profession itself. Never should knowledge and skills be used in the carrying out of oppression.

ACKNOWLEDGMENTS

This work was supported in part by Project #MCI-361011-03 from Maternal and Child Health Bureau (Title V, Social Security Act), Health Resources and Services Administration, and Department of Health and Human Services.

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